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**811—12.2(169) Extra-label use of veterinary drugs and immunization products.** Any extra-label use of veterinary drugs and immunization products shall be by or under the order of a licensed veterinarian only and shall be subject to the following criteria:

- **12.2(1)** There shall be a veterinarian-client-patient relationship as defined in subrule 12.1(3).
- **12.2(2)** For drugs used in animals not intended for food, there are no marketed drugs and immunization products specifically labeled for the conditions diagnosed; or in the veterinarian's clinical judgment the labeled dosage is inappropriate for the condition or the extra-label use should result in a better outcome for the patient.
- **12.2(3)** The health of the treated animal(s) is immediately threatened, and suffering or death would result from a failure to treat the affected animal(s).
- **12.2(4)** Appropriate withdrawal times shall be specified when the veterinary products are used in animals intended as food. Extra-label drug use in food-producing animals must follow Food and Drug Administration Animal Medicinal Drug Use Clarification Act regulations (21 Code of Federal Regulations 530).